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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,671	06/25/2003	James Roy Maxwell	1391/1555	4734
28455	7590	11/29/2005	EXAMINER	
WRIGLEY & DREYFUS 28455 BRINKS HOFFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,671	Applicant(s) MAXWELL ET AL	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) 42-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment, response and Terminal Disclaimer filed on September 14, 2005 has been received and entered into the case. Claims 1 – 70 are pending; claims 42 – 70 are withdrawn from consideration; claims 1 – 41 have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim objections are withdrawn due to amendment.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 17 – 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a composition comprising a pullulan free, edible film comprising an effective amount of a film forming agent and an effective amount of antimicrobial agent

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comprising magnolia bark extract, wherein the antimicrobial agent comprises about 1 – 10%, 8% or 5% of the film. However the specification as originally filed does not describe a film comprising about 1 – 10% of any antimicrobial agent, but only wherein the film comprises about 1 – 10% of magnolia bark extract. Although magnolia bark is an antimicrobial agent, the claims as amended do not require that 1 – 10% of magnolia bark be present, but that 1 – 10% of any antimicrobial agent be present, wherein it comprises some amount of magnolia bark. Thus, the specification as originally filed fails to describe a film where any antimicrobial agent is present at the claimed amounts. This is a new matter rejection.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17 – 19 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 – 19 are drawn to a composition, however are rendered vague and indefinite because it remains unclear if the magnolia bark or antimicrobial extract comprises 1 – 10, 8 and 5% of the edible film, or if the edible film comprises 1 – 10, 8 or 5% of magnolia bark extract or antimicrobial extract.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow et al. (WO 02/43657 A2) in view of Nanba and/or Scherl.

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising magnolia bark extract. The film forming agent comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts, gelatin, processed starch, cellulosic materials,

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alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene, CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint, mint, clove, wintergreen and combinations thereof; menthol, eucalyptus, thymol and combinations thereof. The composition further comprises an effective amount of emulsifier; that

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is selected from lecithin, (C10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitan monopalmitate, sorbitan monostearate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof.

Barklallow teaches a pullulan free edible film comprising a film forming agent, filler, plasticizing agent (softener), medicaments and additives for treating halitosis, plaque, or gingivitis (abstract). The film forming agent is present at 10 – 90% and is selected from cellulose ether, modified starches, natural gums, polymers, hydrocolloids, seaweed, land plant extrudates and combinations thereof (p.2), gum arabic, guar gum, carageenan gum, ghatti, xanthum gum, locust gum and combinations thereof (p.6), alginates and/or pectin (p.7). The filler is present at 10 – 90% and is selected from magnesium carbonate, calcium carbonate, calcium phosphate, magnesium and calcium silicates, limestone, clay, talc, titanium dioxide, microcrystalline cellulose, cellulose polymers, wood and combinations thereof (p.7). The plasticizing agent is present at about 0 – 20 or 2 – 8% and is selected from sorbitola, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof (p.7-8). The film further comprises a medicament selected from pH control agents, oral care agents, breath freshening agents, pharmaceutical agents, nutraceutical agents, saliva stimulating agents, vitamins, mineral and combinations thereof, urea, caries control agents, phosphates, fluorides, chlorohexidine, CPC, triclosan, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof, zinc gluconate, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, anise and menthol (p.8-9). Other additives include coloring agents, flavoring agents and emulsifiers (p.9). The flavors are present at 0.1 –

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20% or 10 – 15% and may be selected from essential oils, synthetic flavors, flavors derived from fruit (p.9). Emulsifiers may include hydrogenated vegetable oils (p.10) and/or lecithin (examples 1-12). The compositions further comprise maltodextrin (examples 1 – 4).

Barkalow does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present. However Barkalow does teach the medicaments may be agents for preventing dental caries, anti-plaque agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Barkalow, since it was a well known agent for preventing dental caries, plaque and gingivitis, as evidenced by Nanba and Scherl. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Barkalow, with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

Barkalow does not teach each of the claimed ingredients in the claimed amounts. However, since such ingredients and additives are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of film forming

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agents in the film of Barkalow, with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

8. Claims 1 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zyck (US 6740332) in view of Nanba and/or Scherl.

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising magnolia bark extract. The film forming agent comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts, gelatin, processed starch, cellulosic materials, alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent

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selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene, CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint; mint, clove, wintergreen and combinations thereof; menthol, eucalyptus, thymol and combinations thereof. The composition further comprises an effective amount of emulsifier; that is selected from lecithin, (c10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monostearate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof.

Zyck teaches pullulan free, edible films comprising maltodextrins, hydrocolloids and fillers (abstract). The films further comprise medicaments and other additives for providing oral care, cleansing and breath freshening (abstract), to include softeners, colorants, flavors and emulsifiers (col.3 line 1-10). The maltodextrin is present at about 5 – 60 or 20 – 40%, the hydrocolloid is present at about 10 – 50% or 20 – 30% and the filler is present at about 5 – 30%

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or 15 – 20% (col.3-4). Hydrocolloids are selected from natural seaweeds, natural seed gums, natural plant extrudates, natural fiber extracts, biosynthetic gums, gelatins, processed starch, cellulose materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, tara gum, gum Arabic, ghatti hum agar gum, xanthum gum, pectin, and combinations thereof (col.3 line 50-63). Fillers include microcrystalline cellulose, cellulose polymers, wood, magnesium and calcium carbonate, ground limestone, silicates such as magnesium and aluminum, clay, talc, titanium dioxide, mono, di, and/or tri-calcium phosphates (col.3 line 64 – col.4 line 8). Medicaments include oral cleansing, breath freshening agent selected from pH control agents, urea, inorganic components for tartar/caries control, phosphates, fluorides, breath freshening agents, zinc gluconate, anti-plaque agents, anti-gingivitis agents, chlorhexidene, CPC, triclosan, saliva stimulating agents, food acid, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, and/or tartaric acids, pharmaceutical agents, nutraceutical agents, vitamins, minerals or combinations thereof (col.4 cline 19-34). Softening agents are present at about 0 – 20% or 2 – 10% and are selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof (col.4 line 52-61). Flavoring agents are present at about 0.1 – 20% or 10 – 15% and are selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, menthol, eucalyptus, thymol and combinations thereof (col.5 line 1-12). The emulsifiers are selected from lecithin, (C10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof (col.5 line 13-22)

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Zyck does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present. However Zyck does teach the medicaments may be agents for preventing dental caries, anti-plaque agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Zyck, since it was a well known agent for preventing dental caries, plaque and gingivitis, as evidenced by Nanba and Scherl. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Zyck, with a reasonable expectation for successfully obtaining the effective edible film of Zyck.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 41 of copending Application No. 10/604,920 in view of Nanba and/or Scherl.

The claims of the above application recite an edible film similar to that as claimed. They do not teach the film compositions wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present. However they do teach the medicaments may be agents for preventing dental caries, anti-plaque agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the films of the claimed compositions, since it was a well known agent for preventing dental caries, plaque and gingivitis, as evidenced by Nanba and Scherl. In addition, since such

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medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract, with a reasonable expectation for successfully obtaining the compositions of the claims.

This is a provisional obviousness-type double patenting rejection.

It is noted that applicant has submitted a terminal disclaimer over other, related, pending applications. However, the above application number is not correctly identified. Specifically, the terminal disclaimer submitted refers to application number 604920, where the instant provisional rejection is over application number 10/604,920. This rejection will be withdrawn upon submission of a terminal disclaimer which correctly identifies the pending application number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
November 25, 2005
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A handwritten signature in black ink, appearing to read 'R. Davis', is positioned to the right of the typed name and date.